INTERNATIONAL STANDARD

ISO 7886-3

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Sterile hypodermic syringes for single use —

Part 3: Auto-disable syringes for fixed-dose immunization

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7886-3 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

ISO 7886 consists of the following parts, under the general title *Sterile hypodermic syringes for single use*:

— *Part 1: Syringes for manual use*

— *Part 2: Syringes for use with power-driven syringe pumps*

— *Part 3: Auto-disable syringes for fixed-dose immunization*

— *Part 4: Syringes with reuse prevention feature*

For the purposes of this part of ISO 7886, the CEN annex regarding fulfilment of European Council Directives has been removed.

Introduction

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts, ISO 7886-1 retaining essentially the scope of ISO 7886:1984, and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this third part of ISO 7886 was recognized as a high priority requirement to prevent the re-use of fixed dose immunization syringes in the developing and transitional countries. Re-use of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens.

The World Health Organization had produced a specification for syringes that are rendered inactive after use (commonly referred to as "auto-disable" syringes). Both the WHO and ISO agreed that an additional part of ISO 7886 would be required to cover "auto-disable" syringes, whilst leaving in place ISO 7886 Parts 1 and 2 without modification, as a large number of devices in common use would not be intended to comply with the auto-disable properties suggested.

This part of ISO 7886 is intended to cover "fixed dose" immunization syringes that are rendered inoperable after delivery of the intended dose. These syringes are not covered by Parts 1 and 2 of ISO 7886.

It is recognized that syringes designed to reduce the risk of needlestick injuries, in addition to preventing sharps injuries, may also comply with this part of ISO 7886 with regard to their auto-disable properties, but it is stressed that anti-needlestick properties of syringes are not in themselves addressed in this part of ISO 7886.

Sterile hypodermic syringes for single use —

Part 3:
Auto-disable syringes for fixed-dose immunization

1 Scope

This part of ISO 7886 specifies the properties and performance of sterile single-use hypodermic syringes with or without needle, made of plastic materials and stainless steel and intended for the aspiration of vaccines or for the injection of vaccines immediately after filling. Upon delivering a fixed dose of vaccine, the syringe is automatically rendered unusable.

This part of ISO 7886 does not specify the design of the auto-disable feature, which is left to the discretion of the manufacturer.

This part of ISO 7886 is not applicable to syringes for use with insulin (specified in ISO 8537), syringes made of glass (specified in ISO 595), syringes for use with power-driven syringe pumps (specified in ISO 7886-2), auto-disable syringes for variable dose delivery and syringes designed to be prefilled. It does not address compatibility with injection fluids/vaccines.

NOTE A fourth part of ISO 7886 is being prepared to cover syringes with reuse prevention feature.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:1991, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*